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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,340	12/04/2003	Dirk Jager	LUD-5793.1 CIP	3224
24972	7590	07/26/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			HALVORSON, MARK	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 07/26/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/729,340

Applicant(s)

JAGER ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 10-14, 58-60, 83-92, 113 and 114 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 10-14, 58-60, 83-92, 113 and 114 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1, 10-14, 58-60, 83-92, 113 and 114 are pending in the Application.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 10-12, 14, 83, 84, 89-91, and 113 drawn to an isolated nucleic acid molecule, classified in class 536, subclass 23.1.
  - II. Claims 13, 58-60, 85-88, 92 and 114 drawn to an isolated peptide, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I is related to the protein of Group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the claims include distinct sequences inclusive of various complements and fragments. This search requires an extensive analysis of the art

retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above: furthermore, a search of the nucleic acid molecules of claims 13, 58-60, 85-88, 92 and 114 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of Group II. As such, it would be burdensome to search the inventions of Groups I and II.

3. This application further contains claims directed to the following patentably distinct inventions.

Groups I-II are further subject to election of a single disclosed nucleic acid or polypeptide.

Claims 10, 83, 84, and 89 drawn to nucleic acids,

Claims 1, 13, 85 drawn to a polypeptides,

are generic to groups I-II as they are drawn specifically to nucleic acids and polypeptides, wherein the inventions are drawn to

**nucleic acids of SEQ ID NOs: 1, 2, 3, 4, 5, 8, 15, 19, 22, 26 or 31 and nucleic acids that encode SEQ ID NOs: 23 and 30.**

**polypeptides of SEQ ID NOs: 5, 7, 16, 19, 23, 27, 30, 32 and polypeptides encoded by the nucleic acid of SEQ ID NOs: 1, 3, 4, 8, 15, 19, 22, 26 or 31.**

Claims 10, 83, 84, 89 and Claims 1, 13, 85 are drawn to nucleic acids and polypeptides that fail the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share, as a whole, a substantial structural feature disclosed as being essential to that utility. However, the molecules of each of claims 1, 10, 13, 83-85, 89 do not share as a whole, a substantial structural feature, one with the other because Claims 10, 83, 84, 89 are drawn to nucleic acids with structurally different nucleic acid sequences and Claim

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1, 13, 85 are drawn to polypeptides with structurally different polypeptide sequences, and therefore do not have as a group similar structures.


Thus each of these claims fail the Harnish test and they do not meet the requirements to be accorded Markush practice under MPEP 803.02. Applicant must elect not only a single Group but also a single nucleic acid or polypeptide for examination.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD  
Patent Examiner  
571-272-6539

  
**MISOOK YU**  
**PATENT EXAMINER**